510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: November 19, 2013

Applicant: Mölnlycke Health Care US, LLC

5550 Peachtree Parkway, Suite 500

Norcross, GA 30092

Registration number: 3004763499

Owner/Operator Number: 9067000

Official Correspondent: Angela L. Bunn, RAC

Director, Regulatory Affairs of the Americas

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Trade/Proprietary Name: Mepitel® Ag

Common Name: Wound and Burn Dressing

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Predicate Device Name(s): Mepitel® and Urgotul® Ag

Description of Device:

Mepitel Ag is a soft silicone wound contact layer that allows exudate to pass vertically into a secondary dressing.

Mepitel Ag makes it possible to change only the secondary absorbent dressing. It maintains its structural integrity and can be left in place for up to eight (8) days depending on the wound condition and surrounding skin (or as indicated by accepted clinical practice).

In vitro testing demonstrates that Mepitel Ag gives a ≥4 log reduction, on the dressing, of the following Gram positive bacteria, Gram negative bacteria and yeast; *Enterococcus feacalis* (VRE), *Staphylococcus aureus* (MRSA), *Staphylococcus epidermidis, Acinetobacter baumanii, Enterobacter cloacae, Pseudomonas aeruginosa, Candida albicans, Candida guillermondi, Candida lusitiane.* The dressing sustains antimicrobial activity for up to eight (8) days in *in vitro* studies. By reducing the number of micro-organisms, Mepitel Ag may also reduce odour.

Mepitel Ag has shown to have a 4 log microbial reduction up to eight (8) days when tested *in vitro* with a secondary dressing.

Mepitel Ag maintains a moist wound environment in combination with a secondary dressing.

Mepitel Ag can be used under compression bandaging.

Mepitel Ag consists of:

1. a Safetac adhesive layer containing silver sulphate and cellulose compound. Safetac is a unique and a patented adhesive technology.
2. a polyamide net

Contents of the dressing: Polydimethylsiloxane, Polyamide, Silver sulphate, Sodium carboxymethylcellulose.

The product and its packaging are not made with natural rubber latex.

Intended Use/Indication for Use:

Mepitel® Ag is intended for the management of a wide range of exuding wounds such as skin tears, skin abrasions, sutured/surgical wounds, partial thickness burns, partial and full thickness grafts, lacerations, diabetic ulcers, venous ulcers, and arterial ulcers. Silver Sulphate is added to the dressing as a preservative to inhibit or reduce microbial growth on the dressing.

Performance Data:

The following *in vitro* performance testing was completed on the proposed device:

- Antimicrobial effect against 9 strains
- Antimicrobial effect on the dressing against P.a, S.a and C.a

All areas performed as expected to provide a level of effectiveness deemed necessary for the intended us of this device.

Clinical Testing:

No clinical data was required.

Conclusion:

Based on the information presented in this submission, it can be concluded that the Mepitel® Ag is equivalent to the Mepitel® (K984371) and the Urgotul® Ag (K100430) predicate devices with respect to intended use, materials, design, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Mölnlycke Health Care US, LLC
Ms. Angela L. Bunn, RAC
Director, Regulatory Affairs for the Americas
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

Re: K130040
Trade/Device Name: Mepitel® Ag
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 10, 2014
Received: January 10, 2014

Dear Ms. Bunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130040

Device Name: Mepitel® Ag

Indications For Use:

Mepitel® Ag is intended for the management of a wide range of exuding wounds such as skin tears, skin abrasions, sutured/surgical wounds, partial thickness burns, partial and full thickness grafts, lacerations, diabetic ulcers, venous ulcers, and arterial ulcers. Silver Sulphate is added to the dressing as a preservative to inhibit or reduce microbial growth on the dressing.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S